

## REVIEW ARTICLE

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# Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques

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### ABSTRACT

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**Introduction.** Gender reassignment surgery is the keystone of the treatment of transgender patients. For male-to-female transgenders, this involves the creation of a neovagina. Many surgical methods for vaginoplasty have been opted. The penile skin inversion technique is the method of choice for most gender surgeons. However, the optimal surgical technique for vaginoplasty in transgender women has not yet been identified, as outcomes of the different techniques have never been compared.

**Aim.** With this systematic review, we aim to give a detailed overview of the published outcomes of all currently available techniques for vaginoplasty in male-to-female transgenders.

**Methods.** A PubMed and EMBASE search for relevant publications (1995–present), which provided data on the outcome of techniques for vaginoplasty in male-to-female transgender patients.

**Main Outcome Measures.** Main outcome measures are complications, neovaginal depth and width, sexual function, patient satisfaction, and improvement in quality of life (QoL).

**Results.** Twenty-six studies satisfied the inclusion criteria. The majority of these studies were retrospective case series of low to intermediate quality. Outcome of the penile skin inversion technique was reported in 1,461 patients, bowel vaginoplasty in 102 patients. Neovaginal stenosis was the most frequent complication in both techniques. Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. QoL was only reported in one study. Comparison between techniques was difficult due to the lack of standardization.

**Conclusions.** The penile skin inversion technique is the most researched surgical procedure. Outcome of bowel vaginoplasty has been reported less frequently but does not seem to be inferior. The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools, and follow-up. Standardized protocols and prospective study designs are mandatory for correct interpretation and comparability of data. **Horbach SER, Bouman M-B, Smit JM, Özer M, Buncamper ME, and Mullender MG. Outcome of vaginoplasty in male-to-female transgenders: A systematic review of surgical techniques. J Sex Med 2015;12:1499–1512.**

**Key Words.** Vaginoplasty; Transsexualism; Gender Identity Disorder; Sex Reassignment Surgery; Penile Inversion Vaginoplasty; Bowel Vaginoplasty

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### Introduction

The phrases “Gender Identity Disorder” and “Gender Dysphoria” apply to patients with a strong and persistent cross-gender identification, a

persistent discomfort with their anatomical sex, and a sense of inappropriateness in the gender role of that sex, which causes significant distress in social, occupational, and other important areas of functioning. This commonly leads to the belief of

being born in the wrong sex and a preoccupation with losing secondary sexual characteristics of the anatomical sex [1,2].

The importance and potential benefits of genital sex reassignment surgery (SRS) were first advocated by Harry Benjamin, with the release of his book “The Transsexual Phenomenon” [3] in 1966 [2,4]. Since 1979, the Harry Benjamin International Gender Dysphoria Association (now World Professional Association for Transgender Health) has been establishing evidence-based “Standards of Care”: guidelines for diagnostics and treatment of transgender patients. These clinical guidelines provide a stepwise procedure that consists of diagnostic assessment, real-life experience and psychotherapy, hormone therapy, and surgical therapy [5].

The advantages of therapy for gender dysphoric patients have been pointed out by various studies in the past decades. Recently, a large-scale study by de Vries et al. [6] found a significant improvement in psychological functioning and well-being of transgender adolescents after hormonal and surgical therapy. Most transgenders indicate an improvement in sex life and report more sexual excitement after SRS [7]. For male-to-female (MtF) transgenders, a correlation was seen between neovaginal anatomy and satisfaction with the neovagina and sexual functioning [7,8].

Nowadays, treatment of patients with gender dysphoria is becoming more and more accepted by the general public and surgical treatment for especially MtF transgenders is performed worldwide.

For MtF transgenders, the core surgical procedures are orchidectomy, penectomy, clitoroplasty, labiaplasty, and creation of the neovagina, together often referred to as “(neo)vaginoplasty.” Other common surgical procedures for the establishment of a feminine aesthetic appearance are breast augmentation, facial feminization surgery, permanent hair removal, lipoplasty, and thyroid chondroplasty [9,10]. In the fields of gynecology, urology, and reconstructive plastic surgery, many surgical techniques for vaginal (re)construction have been described [2,10–13]. Not only MtF transgenders but also biological women with disorders of sexual development (such as Mayer-Rokitansky-Kustner or intersex disorders) and those who underwent vaginectomy after malignancy or trauma are possible candidates for vaginoplasty.

In transgender vaginoplasty, surgical techniques can be divided in three main categories, based on the origin of the donor tissue [2,14]:

1. Skin grafts.
2. Penile-scrotal skin flaps.
3. Pedicled small or large bowel segments.

Experimental options for creating a neovagina are the use of buccal mucosa, amnion grafts, or decellularized tissue. Most gender surgeons prefer the use of inverted penoscrotal skin flaps. However, it is still unclear what the optimal surgical technique is, as the outcomes of the available surgical techniques have never been compared.

### Key Objectives

Our main goal is to give an overview of available surgical techniques for vaginoplasty, and their outcomes in MtF transgender patients, by reviewing all published data in the past 20 years. Ideally, this would make it possible to identify the best available technique for vaginoplasty in MtF transgenders. Our second goal is to reveal gaps in current literature, which can form the basis for further research.

### Methods

For this systematic review, data collection and analysis was performed according to the guidelines of the PRISMA statement 2009 [15]. Inclusion criteria and methods of analysis were specified in advance.

### Search Strategy

We have performed a broad systematic search in Medline and EMBASE bibliographic databases for studies that report the outcome of vaginoplasty in MtF transgenders. This search strategy was peer reviewed by an information specialist at the VU University medical library.

A search strategy was made using a combination of (MeSH) terms such as *neovagina*, *vaginoplasty*, *transsexualism*, and synonyms (Table 1). The PubMed function “Cited references” and reference lists of all included articles were screened for additional relevant literature. A database of retrieved articles was made using Reference Manager 2012 (Thomson Reuters), and all duplicates were removed from our database.

### Study Selection

The first selection was made based on title and abstract without blinding to authorship or journal by one author (S.H.). Remaining articles were analyzed by two independent researchers (S.H. and

**Table 1** Search strategy EMBASE and PubMed**PubMed/MEDLINE**

(vaginoplast\*[tiab] OR neovagina\*[tiab] OR vaginoplast\*[ot] OR neovagina\*[ot]) AND  
 ("Transsexualism"[Mesh] OR "Sex Reassignment Procedures"[Mesh] OR "Transgendered Persons"[Mesh] OR "Health Services for Transgendered Persons"[Mesh] OR sex reassignment\*[tiab] OR sex change\*[tiab] OR gender reassignment\*[tiab] OR transsex\*[tiab] OR gender change\*[tiab] OR transgender\*[tiab] OR intersex\*[tiab] OR gender identity disorder\*[tiab] OR sex reassignment\*[ot] OR sex change\*[ot] OR gender reassignment\*[ot] OR transsex\*[ot] OR gender change\*[ot] OR transgender\*[ot] OR intersex\*[ot] OR gender identity disorder\*[ot])

**EMBASE**

"vagina reconstruction"/exp OR vaginoplast\*:ab,ti OR neovagina\*:ab,ti OR (vagina NEAR/3 reconstruct\*):ab,ti OR (vaginal NEAR/3 reconstruct\*):ab,ti OR colovagin\*:ab,ti

AND

("transsexuality"/exp OR "transsexualism"/exp OR "sex reassignment"/exp OR (sex NEAR/3 reassignment\*):ab,ti OR (sex NEAR/3 change\*):ab,ti OR (gender NEAR/3 reassignment\*):ab,ti OR transsex\*:ab, ti OR (gender NEAR/3 change\*):ab,ti OR transgender\*:ab,ti OR ("gender identity" NEAR/3 disorder\*):ab,ti)

-Additional use of terms "vaginal reconstruct\*" and "colovagin\*" did not retrieve extra relevant items

-MeSH = Medical Subject Heading, Tiab/ab,ti = Title and abstract

-Date search PubMed january 22th 2014, EMBASE may 21<sup>st</sup> 2014; last search for updates july 2014

M.B.) based on full text. Articles that met all inclusion criteria (as shown in Table 2) were included in the systematic review. No restrictions were imposed with regard to study design and surgical background of the author. If eligibility was doubtful, articles were discussed by the investigators and were in- or excluded based on consensus.

**Data Extraction and Data Analysis**

Information from each included trial was extracted by one author (S.H.) and categorized based on (i) number of (MtF) patient group; (ii) type of surgical technique used for the creation of the neovagina; and (iii) type of outcome measure, including long- and short-term complications, sexual function, aesthetic outcome, patient satisfaction, and quality of life (QoL). The extracted data from each included article were checked and confirmed by the second author (M.B.).

Quality assessment of the studies was performed using the Quality Assessment Tool for Quantitative studies of the Effective Public Health Practice Project, which grades the papers as "weak," "moderate," or "strong" based on six different domains (selection bias, study design, confounders, blinding, data collection methods and withdrawals, and drop-outs) [16].

A statistical analyst at the VU University Medical Center was consulted to determine which method was applicable for statistical analysis of the retrieved data. Only studies that explicitly reported on a particular outcome were taken into account in the analysis of that specific outcome variable. Due to heterogeneity of the outcome measures and patient groups, meta-analysis of the pooled data was impossible [17]. Only when outcome measures were identical, a mean percentage was calculated.

**Results**

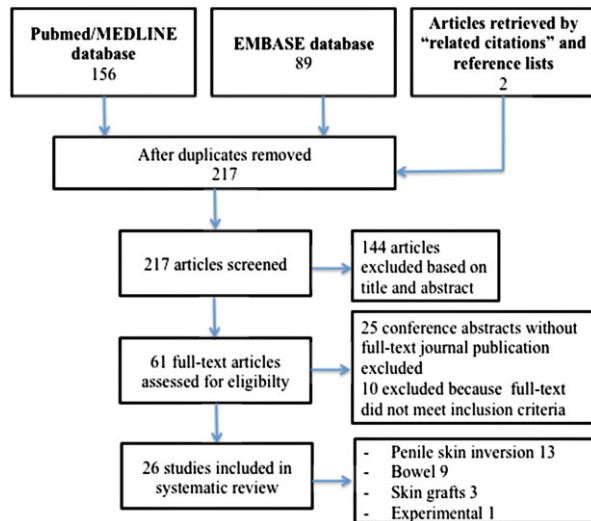
With our initial literature search, a total of 216 references were retrieved, ultimately 25 studies examining the outcome of neovaginoplasty in MtF patients were included in our systematic review (Figure 1). A large number of 25 conference abstracts had to be excluded, because subsequent full-text journal publications were unavailable.

**Skin Grafts**

In this literature search, only three eligible articles were found in which local nongenital skin flaps, full-thickness graft (FTG) or split-thickness skin grafts (STG) were used for the creation of the

**Table 2** Inclusion and exclusion criteria

Inclusion criteria:	Exclusion criteria:
✓ Patient group of n ≥ 5 male-to-female transgenders	x Patient groups consisting only of patients other than MtF transgenders, e.g., patients with vaginal aplasia or vaginectomy
✓ All ages	x Surgical techniques for partial reconstruction of the vagina or correction of complications after vaginoplasty
✓ All techniques for complete vaginoplasty	x Surgical techniques only for creation of neoclitoris or labioplasty
✓ Publication year >1994	x Unspecified surgical technique
✓ Article reports at least one outcome measure; e.g., complications, patient satisfaction, sexual function or QoL	
✓ Follow-up of at least 0.5 year	



**Figure 1** Flow diagram of study selection according to PRISMA

neovagina. All were retrospective studies published in the period of 1995–1998 (Table 3) [13,18,19].

Hage and Karim [18] obtained a full-thickness skin graft from the lower abdomen of six MtF patients and used a mold to insert it in the neovaginal cavity. The mold was removed after 8 days. In a follow-up of 7 months, they saw no postoperative complications and stated that “all patients were pleased with the neovaginal results” and that “sexual intercourse was possible and satisfactory for all patients.” Mean depth was 12 cm, and mean width was 3 cm.

Huang [19] used two different surgical techniques. In a group of 12, the new vagina was constructed out of a penile skin flap and an STG; in the second group of 109 patients, the neovagina consisted out of penile skin flap and an extended inguinopudendal neurovascular island pedicle flap (included the inferolateral portion of the scrotal sac and the medial skin of the inguinal crease). In the first group, vaginal stenosis was seen in 33% and urethral meatus stricture in 0%. In the second study group, these percentages were, respectively, 0% and 6%. Depth was estimated on 8–10 cm. Patient satisfaction was not mentioned.

In a group of 11 MtF transgenders, Siemssen and Matzen [13] used FTG of penile skin, STG, or a combination of both. Overall, vaginal stenosis was present in 45% of patients (n = 5) but with STG alone in 100%. Other complications were defects of transplanted skin (n = 5), hematoma (n = 4), fistula (n = 2), vaginal prolapse (n = 2), and

**Table 3** Study characteristics and outcome of vaginoplasty with nongenital skin flaps and skin grafts

Study	Study design	Quality assessment	N (Total/ MTF)	Surgical technique	Outcome full-thickness skin graft	Outcome complications	Outcome anatomy neovagina	Outcome sexual function	Outcome patient satisfaction	Outcome QoL	Follow-up
Hage and Karim [18]	Retrospective	Weak	MTF 5	Abdominal full-thickness skin graft	No postoperative complications (FU 7 months)		Depth mean 12 cm Width mean 3 cm	“Sexual intercourse was possible and satisfactory for all patients” (100%)	“all patients were pleased with the neovaginal result” (100%)	—	Mean 7 months (3–18 months)
Huang [19]	Retrospective	Weak	MTF 121	1. Penile skin graft/ flap + split-thickness skin graft 12 2. Inguinopudendal skin flaps 109	Vaginal stenosis 1. 4/12 (33%) 2. 5/109 (5%) Urethral meatus stricture 1. 0/12 (0%) 2. 7/109 (6%)		Depth possibly 8–10 cm	—	—	—	>6 months
Siemssen and Matzen [13]	Retrospective	Weak	MTF 11	Full-thickness skin graft penis (4) Combined with STG or FTG (4) Split-thickness skin graft alone (3)	Vaginal stenosis 5/11 (45%) STG alone: 100% Vaginal defects in transplanted skin 5/11 (45%) Hematoma/hemorrhage 4/11 36% Fistula 2/11 (18%) Vaginal prolapse 2/11 (18%) Infection 1/11 (9%)		—	—	—	—	(0–86 months)

FTG = full-thickness skin graft; FU = follow-up; MTF = male-to-female; STG = split-thickness skin graft



infection (n = 1). Neovaginal depth and width were not reported, and patient satisfaction and QoL were not mentioned.

#### *Penoscrotal Skin Flaps (Penile Skin Inversion Technique)*

For many gender surgeons, the method of choice for vaginoplasty is the “penile skin inversion technique,” in which inverted penile skin on an abdominal or inferior pedicle is used as an outside-in skin tube for the lining of the neovagina [2,20]. It can be split open to form a rectangular flap, and it can be combined with a urethral flap [21] or scrotal flaps of multiple designs.

A total of 12 (10 retrospective and two prospective) original studies were found in which the penile skin inversion technique was used, with or without an additional scrotal flap, in a total of 1,461 patients. One review was included [10]. Study characteristics and outcomes of these articles are shown in Table 4.

#### *Neovaginal Anatomy*

Mean neovaginal depth ranged from 10 cm to 13.5 cm. The shallowest neovagina reported was 2.5 cm and the deepest 18 cm. The mean width of the neovagina was 3–4 cm, only described in one study [22]. Perovic et al. [21] categorized the width of 87 neovaginas in “small” (9%), “medium” (77%), or “large” (14%) groups, estimated by the diameter of the vaginal stent that was used. No information was available about the exact measurements of the vaginal stents or neovaginas in this study.

#### *Complications*

*Genital Region.* Neovaginal stricture was reported in six studies [21,22,26,28,30,31]. Stricture of the neovaginal introitus was present in 84 of 674 studied patients (12%, range 4.2–15%). In most cases, a U-shaped introitus plasty was performed, but recurrence rates after correction were not reported in the available literature. In Jarolim [26], a second operation was necessary to “free the introitus” for easier penetration at later date in 12 of 29 patients (41%). In 43 patients of a total of 582 (7%, range 1–12%), stricture of the vagina other than the introitus was reported. Vaginal shrinkage was seen in 2–10% of treated patients [21,32].

Partial necrosis of the neovagina ranged from 2.7% to 4.2% [22,23,31] and clitoral necrosis ranged from 1% to 3% [27,28,30]. Namba et al.

[29] used an M-shaped perineoscrotal flap in addition to an inverted penile skin flap for the lining of the neovaginal cavity. In this small group of six patients, there was necrosis of two scrotal flaps (33%). Neovaginal (posterior) wall rupture was seen in one patient after sexual intercourse in a group of 87 and was only described by Perovic et al. [21], who used a urethral flap for the anterior neovaginal wall. Genital pain was present in 9% [28] and 3% [31] in patient groups of, respectively, 232 and 332 MtF patients.

In four studies [10,21,22,29] with a total of 917 MtF patients, nine cases of rectovaginal fistula were reported, with a mean percentage of 1% (range 0.8–17%). The prevalence of neovaginal prolapse was 1–2% in four studies [23,27,30,31]. All surgeons in these studies had fixated the neovagina with sutures to the surrounding connective tissue during initial surgery; fixation to the sacrospinous ligament was not reported. Only two studies report secondary cosmetic corrections in 54% [22] and 31% [26] of patients.

*Urinary Tract.* Hoebeke et al. [25] are the only authors who investigated the impact of sex reassignment surgery on the lower urinary tract system in a group of 31 MtF patients. Changed voiding after SRS was reported in 32% of these patients (better 13%, same 68%, worse 19%). Six of these patients (19%) suffered from involuntary loss of urine at a mean follow-up of 3 years after surgery, two were cases of urge incontinence, two stress incontinence, one mixed incontinence, and one patient complained of dribbling. Urinary infection was seen in 10 patients (32%), with a mean episode rate of 1.7. Of the patients who were sexually active, 15% (4 out of 27) had a urinary infection after vaginal sex.

Meatal stenosis was reported in five original studies [21,22,27,28,30] with a mean percentage of 5% (33 out of 658) and a range of 1–6%. Selvaggi and Bellringer [10] claim that meatal stenosis is present in 3–4% of cases, referring to their own unpublished work. Rossi Neto et al. [31] saw meatal stenosis as the most frequent complication related to the surgery, 40% of their patients presented with an obstructive voiding disorder (with symptoms varying from involuntary urine loss to urine retention) due to meatal stenosis for which a simple Y-V plastic reconstruction was performed in a second surgery. Fifteen percent of these patients needed a second correction because of stricture recurrence. Only one case of urethral prolapse was described in literature [21].

**Table 4** Study characteristics and outcome of penile skin inversion technique

Study	Study design	Quality assessment	N (Total/ MTF)	Surgical technique	Outcome complications	Outcome Anatomy neovagina	Outcome sexual function	Outcome patient satisfaction	Outcome QoL	Follow-up
Amend et al. [22]	Retrospective	Moderate	MTF 24	Penile inversion	Intraoperative: Rectal injury 1 (4.2%) Bleeding 2 (8.3%) Postoperative: Recto-neovaginal fistula 1 (4.2%) Cerebral ischemia 1 (4.2%) Bleeding 2 (8.3%) Meatal stenosis 1 (4.2%) Transient urinary incontinence 2 (8.3%) Neovaginal introitus stricture + labia asymmetry 1 (4.2%) Partial necrosis 1 (4.2%) Secondary post-operative cosmetic corrections 13 (54.2%)	Depth mean 11 cm (range 10–14 cm) Width 3–4 cm	Regular sexual intercourse 8 (33%) (no pain reported) Neocitoral sensation Excellent 18 (78%) Good 5 (19%) Unsatisfactory 1 (4.2%) Hair growth 0 (0%)	Satisfaction with neovaginal depth 24 (100%) Regret 1 (4%)	Mean 39.7 months (19–69 months)	
Goddard et al. [23]	Retrospective	Moderate	MTF 233 Early follow-up 197 Late follow-up 70	Penile inversion	Perioperative: Infection requiring AB treatment 15 (16.8%) MRSA infection 2 Bleeding 7 (3.2%) Necrosis 6 (2.7%) Vaginal prolapse 2 (1.8%) DVT 2 (0.9%) Pulmonary embolism 1 (0.5%) —	Early FU (mean 56 days): Depth mean 13 (range 5–15) Late FU (mean 3 years): Depth mean 13.5 (range 2.5–18)	Ability to achieve orgasm 75/91 (82.4%), easily 20.9%, usually easily 42.9%, rarely easily 18.7% Intensity of orgasm: More intense 43/77 (55.8%), unchanged 16/77 (20.8%)	Outward appearance: satisfied 61.2%, very satisfied 26.2%, Aesthetic outcome: satisfied 36.2%, very satisfied 38.3% Functional outcome: satisfied 34.4%, very satisfied 38.3%	Life easier after SRS: 68.4%, somewhat easier 14.7%	Mean 56 days (8–351 days)
Hess et al. [24]	Retrospective	Weak	MTF 119	Penile inversion	—	—	—	—	—	Mean 5.05 years (1–7 years)
Hoebke et al. [25]	Retrospective	Moderate	MTF 31	Penoscrotal inversion technique	Changed voiding 10/31 (32%) Better 13% Same 68% Worse 19% Urinary incontinence 6/31 (19%) Urinary infection 10/32 (32%) mean episodes 1.7	—	Sexual intercourse (vaginal) 27/31 (87%) Urinary infection after vaginal sex 4/27 (15%)	—	—	Mean 3 years 8 months (1–12 years)
Jarolim [26]	Retrospective	Weak	MTF 29	Penile inversion	Nocturia 13/31 (41%) Painful granulomas 0% Voiding without difficulties 100% 2nd operation for narrow introitus 12/29 (41%) 2nd operation for reduction labia majora 9/29 (31%)	—	—	—	—	—
Krege et al. [27]	Prospective	Moderate	MTF 66	Penile inversion and 2nd cosmetic correction	Meatal stenosis 7 (5%) Severe wound infection 6 (4%) Rectal lesion 3 (2%) Necrosis of the glans 3 (2%) Vaginal prolapse 2 (1%) Necrosis of distal urethra 1 (0.6%) Lesion of external urethral sphincter 1 (0.6%) Urethral fistula 1 (0.6%)	—	Sexual intercourse 58% Problems with intercourse 25% Dyspareunia 6% Bleeding 3%	Satisfaction with external genitalia 29/31 94% Disapproval of labia minora 2/31 6% Satisfaction with depth 22/29 76% Clitoral orgasm 87%	—	>6 months
Lawrence [28]	Retrospective	Moderate	MTF 232	Penile inversion	Vaginal stenosis at all times 8% Vaginal stenosis during arousal 6% Misdirected urinary stream 33% Urethral stenosis 4% Clitoral necrosis 3% Genital pain 9%	—	Orgasm with masturbation Almost always 36% > 0.5 of time 12% < 0.5 of time 15% Rarely 15% Never 18%	Consistent regret 0 (0%) Some regret 15 (6%) Happiness with sexual function 7.8 (0–10) Happiness with SRS 8.7 (0–10)	Improvement QoL with SRS 7.9 (–2–10)	Mean 3 years (1–7 years)

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Perovic et al. [21]	Retrospective	Weak	MTF 89	Penile inversion and urethral flap	Introitus stenosis 6/87 (7%) Meatus stenosis 1/87 (1%) Urethral prolapse 1/87 (1%) Neovaginal wall rupture 1/87 (1%) Rectovaginal fistula 1/87 (1%) Vaginal shrinkage 2/87 (2%)	Depth mean 11.6 (9–18) Width: 8/87 small (9%) 67/87 medium (77%) 12/87 large (14%)	Surface moisture Satisfactory 71/87 (82%) Unsatisfactory 16/87 (18%) Normal sexual intercourse 69/87 (79%) Orgasm 73/87 (84%)	Aesthetic normal appearance 78/87 (90%)	Mean 4.6 years (0.25–6 years)
Namba et al. [29]	Retrospective	Weak	MTF 6	Inverted penile flap and M-shaped perineoscrotal flap	Partial necrosis scrotal flap 2/6 (33%) Rectovaginal fistula 1/6 (17%)	—	—	"All the patients are satisfied" 100%	—
Reed [30]	Retrospective	Weak	MTF 250	Penile skin inversion	Vaginal stenosis 3 (1%) Labial hematoma 10/250 (4%) Rectal perforation 7/250 (3%) Surgical bleeding 6/250 (2%) Unaesthetic scars/dehiscence 30/250 (12%) Urethral vaginal confluence with intravaginal voiding 2/250 (1%) Urethral spongiosum rest 20/250 (8%) Urethral meatal stenosis 15/250 (6%) Vaginal prolapse 6/250 (2%) Clitoral necrosis 2/250 (1%) Anterior elevation of vulvar plate 10/250 (4%) Stricture of vaginal introitus 53/332 15% Resection of residual corpora 50/332 15% Vaginal stricture 40/332 12% Loss of vaginal depth 25/332 8% Vaginal segment necrosis 9/332 3% Vaginal prolapse 4/332 1% Obstructive voiding disorder 132/332 40% (Meatal) stricture recurrence 20/332 15% Dribbling 26/332 8% Rectal injury 11/332 3% Wound healing disorders 108/332 33% Genital pain 3% Pulmonary emboli 2/1,000 (0.2%) Bleeding 10% Rectovaginal fistula 6/800 (0.8%) Meatal stenosis 3–4% Bleeding 3/50 (6%) Shrinkage of neovagina 10% Rectocele 0% Subcutaneous hematoma 3/50 (6%)	Inadequate depth >5/250 (2%)	—	—	—
Rossi Neto et al. [31]	Retrospective	Weak	MTF 332	Penile inversion	Stricture of vaginal introitus 53/332 15% Resection of residual corpora 50/332 15% Vaginal stricture 40/332 12% Loss of vaginal depth 25/332 8% Vaginal segment necrosis 9/332 3% Vaginal prolapse 4/332 1% Obstructive voiding disorder 132/332 40% (Meatal) stricture recurrence 20/332 15% Dribbling 26/332 8% Rectal injury 11/332 3% Wound healing disorders 108/332 33% Genital pain 3% Pulmonary emboli 2/1,000 (0.2%) Bleeding 10% Rectovaginal fistula 6/800 (0.8%) Meatal stenosis 3–4% Bleeding 3/50 (6%) Shrinkage of neovagina 10% Rectocele 0% Subcutaneous hematoma 3/50 (6%)	—	Dyspareunia 5/332 2%	—	—
Selvaggi and Bellinger [10]	Review	Moderate	MTF 1000	Penile inversion	Stricture of vaginal introitus 53/332 15% Resection of residual corpora 50/332 15% Vaginal stricture 40/332 12% Loss of vaginal depth 25/332 8% Vaginal segment necrosis 9/332 3% Vaginal prolapse 4/332 1% Obstructive voiding disorder 132/332 40% (Meatal) stricture recurrence 20/332 15% Dribbling 26/332 8% Rectal injury 11/332 3% Wound healing disorders 108/332 33% Genital pain 3% Pulmonary emboli 2/1,000 (0.2%) Bleeding 10% Rectovaginal fistula 6/800 (0.8%) Meatal stenosis 3–4% Bleeding 3/50 (6%) Shrinkage of neovagina 10% Rectocele 0% Subcutaneous hematoma 3/50 (6%)	—	—	—	—
Wagner et al. [32]	Prospective	Moderate	MTF 50	Penile inversion	Stricture of vaginal introitus 53/332 15% Resection of residual corpora 50/332 15% Vaginal stricture 40/332 12% Loss of vaginal depth 25/332 8% Vaginal segment necrosis 9/332 3% Vaginal prolapse 4/332 1% Obstructive voiding disorder 132/332 40% (Meatal) stricture recurrence 20/332 15% Dribbling 26/332 8% Rectal injury 11/332 3% Wound healing disorders 108/332 33% Genital pain 3% Pulmonary emboli 2/1,000 (0.2%) Bleeding 10% Rectovaginal fistula 6/800 (0.8%) Meatal stenosis 3–4% Bleeding 3/50 (6%) Shrinkage of neovagina 10% Rectocele 0% Subcutaneous hematoma 3/50 (6%)	Depth mean 10 cm (6–14)	Regular sexual intercourse 42/50 (84%) Dyspareunia 2/50 (4%) Clitoral orgasm 35/50 (70%)	Satisfaction with esthetic results 45/50 (90%) Dissatisfaction with labia majora 5/50 (10%) Satisfaction with neovaginal depth 40/50 (80%)	Mean 3 years

AB = antibiotic; DVT = deep venous thrombosis; FU = follow-up; MRSA = methicillin-resistant *Staphylococcus aureus*; MTF = male-to-female; SFS = sex reassignment surgery

**Gastrointestinal.** Rectal injury was seen by Krege et al. [27] in 2% of patients (3/66), which could be closed primarily in one case and there was need for a temporary colostomy in another case (during surgery). One patient developed a rectovaginal fistula. In the study group of Rossi Neto et al. [31], 3.3% of all patients had rectal injury (11/332); two lesions were closed primarily during surgery. Nine patients developed postsurgical fistulas, for which a transneovaginal surgical correction with a protective colostomy was necessary in seven patients. Amend et al. [22] reported only one case of rectal injury (1/24, 4.2%), which was closed primarily during surgery. In the retrospective study of Reed [30], there were seven rectal perforations in 250 treated patients (3%), but no further specification was given by the author.

**Wound Healing Disorders.** Wound dehiscence was described by Reed [30] and Rossi Neto et al. [31] in, respectively, 12% (30 out of 250 patients) and 33% (108 out of 332 patients). Local abscesses were seen in 5% and subcutaneous hematoma in 4–6% [31,32].

**Unspecific Events.** Surgical bleeding occurred in 3.2–10% [10,22,23,30,32]. The main source of the hemorrhage was the corpus spongiosum surrounding the urethra [10]. Goddard et al. [23] reported deep venous thrombosis in 0.9% and pulmonary embolism in 0.5% of 233 MtF patients, despite stopping feminizing hormones 6 weeks prior to surgery, administering subcutaneous heparin injections, and the use of compression stockings until patient discharge.

### Sexual Function

One hundred sixty-four out of a total of 223 patients in five studies [21,22,25,27,32] were having (vaginal) sexual intercourse after surgery, which corresponds with a mean percentage of 75% (range 33–87%). Dyspareunia was present in 2–6% [27,31,32] and neovaginal bleeding in 3% [27]. Orgasm was possible in 70% [32], 84% [21], and 82.4% [24]. Lawrence [28] asked their 323 patients about the possibility to have an orgasm with masturbation. Answers were divided in different categories: almost always (36%), more than half of the time (12%), less than half of the time (15%), rarely (15%), and never (18%). Hess et al. [24] found that 55.8% of their patients had a more intense orgasm postoperatively, whereas orgasm intensity was unchanged in 20.8%. Surface moisture was satisfactory in 82% of patients and unsat-

isfactory in 18% [21], but it is unclear if these results were reported by the patient or treating physician. On a scale of 0–10, patients rated the happiness with their sexual function after SRS with a 7.8 [28]. Patients were dissatisfied with the functional outcome of their neovagina in 8.7% [24]. Female Sexual Function Index (FSFI) scores or other measurement scores for sexual satisfaction were not available in the included articles.

### Patient Satisfaction and QoL

Three studies [22,27,32] determined patient satisfaction with neovaginal depth, by using a patient questionnaire with “yes or no” answer options. They found that, respectively, 100% [22], 76% [27] and 80% [32] of transgenders were satisfied with the depth of the new vagina (mean percentage 83%). Wagner et al. [32] report that two out of eight dissatisfied patients, who underwent a new operation for neovaginal deepening, were still not satisfied with the results obtained.

Patient satisfaction with aesthetic appearance of the external genitalia was also questioned in a similar manner as described above and was 90–100% [22,27,32]. Degree of satisfaction with aesthetic outcome was assessed in 94 patients and was divided in very satisfied (38.3%), satisfied (36.2%), and mostly satisfied (22.3%) [24]. Outward appearance was (very) satisfying for 84.4% of patients [24]. In one study, patients who disapproved of the aesthetic appearance were dissatisfied with the labia minora [21], despite the fact that a secondary cosmetic correction was included in the standard procedure. In another study, dissatisfaction was attributed to the labia majora [33].

Few patients regretted the surgery. In a study group of 232, none of the patients noted consistent regret, but 6% of patients had some regrets regarding the surgery [28]. On a scale from 0 to 10, patients rated their happiness with the SRS with a 8.7 [28]. Patients indicated that their life was easier in 68.4%, and somewhat easier in 14.7% after the penile skin inversion technique [24].

There is only one study [28] that reports improvement in QoL in patients who underwent penile skin inversion vaginoplasty, using a Likert scale from –10 (most worsening possible) to 10 (most improvement possible). Participants' mean rating of improvement in their QoL after surgery was 7.9 (range –2 to 10). Genital pain was the only complication that was negatively correlated with the improvement in QoL ( $P < 0.05$ ). All measures of satisfaction with genital sensation and



neovaginal dimensions also showed a significant correlation with the improvement in QoL.

### *Pedicle Intestinal Segments*

Probably the second most used vaginoplasty technique in MtF transgenders, which is primarily used when the penile skin inversion technique fails, is the use of pedicled bowel, also referred to as “intestinal vaginoplasty,” “rectosigmoid neocolpopoiesis,” or “ileal vaginoplasty.” This technique was first reported by Baldwin in 1907 in patients with vaginal agenesis [34]. The abdomen is entered by a Pfannenstiel laparotomy, laparoscopy-assisted laparotomy, or total laparoscopy, and the vascular pedicle of the bowel segment is identified (sometimes using ultrasound, transillumination, or test clamping). After harvesting the bowel segment, intestinal continuity is restored primarily by end-to-end anastomosis. The intestinal segment is placed in the neovaginal cavity in an anti- or isoperistaltic direction, and the neovaginal-perineal anastomosis is made. Various perineal incision shapes and local interposition flaps are used to widen the introitus, in an attempt to prevent secondary stenosis [35].

The literature search yielded nine articles in which an intestinal vaginoplasty (rectosigmoid or ileum) was performed in MtF transgender patients (Table 5). One systematic review and eight retrospective studies were included, in which a total of 102 MtF patients were enrolled. In five studies, the studied patient group did not only consist of transgender patients, but also patients with congenital absence of the vagina and vaginectomy were included [33,35,37,38,40]. Results of these mixed patient groups will be mentioned separately and will not be used for calculation of mean percentages. The included systematic review [35] had the largest mixed patient group of 894 patients. A few original transgender studies [37,38,40] within this review were also included in our systematic review. In order to give a better overview of the results in our targeted transgender patient group, these original studies were also reported separately. Data were not pooled, so these results will not be taken into account twice.

### *Neovaginal Anatomy*

In the MtF patient group, the mean depth of the rectosigmoid neovagina was 12 cm and the diameter was 3.4–3.9 cm. The harvested bowel segment of the rectosigmoid colon measured 8–12 cm [37,38].

Measurements of the ileum-derived neovagina were only reported in mixed patient groups. In a study of 86 patients with 12 MtF transgenders, the depth was 15–18 cm and the diameter 2.5–4.0 cm. An ileal segment of 15–20 cm was used [33]. In a group of 900 patients (including approximately 50 transgenders), the sigmoid neovagina was 11.5–13 cm deep with a diameter of 3.7–4 cm and the ileum-derived neovaginas were 10.5–18 cm with a diameter of 2.5–4.5 cm [35].

### *Complications*

Bouman et al. [35] in a review on intestinal vaginoplasty in biological women and transgenders concluded that there was an overall complication rate of 6.4% for the sigmoid neovagina in 686 patients and 8.3% for the ileum neovagina calculated in 169 patients.

*Genital Region.* In a total of 30 (only transgender) patients, enrolled in three studies with small patient numbers [36,39,41], there were 13 cases of neovaginal stenosis (43%) after sigmoid vaginoplasty. In the largest combined gynecological and transgender patient group, stenosis of the vaginal introitus was seen in 8.6% for sigmoid vaginoplasty and 1.2% for ileum vaginoplasty [35]. Two other studies with a considerable transgender subgroup show a percentage of 6% for neovaginal introital stenosis [33,37]. Dilation was performed in most cases, but some authors prefer correction with a Z-plasty and local flaps [37].

Necrosis of the neovagina was only reported in one patient by Karim et al. [41], possibly due to leakage of the intercolic anastomosis. Only two cases of rectovaginal fistula were found in literature [36,37].

Mucosal prolapse of the sigmoid neovagina was only reported in combined patient groups with a mean percentage of 7.7% [35]; prolapse of an ileum-derived neovagina has not been reported in literature.

Discharge and malodor were only mentioned after rectosigmoid vaginoplasty, in, respectively, 0.7% and 9.5% of these patients [35].

None of the included articles report adenocarcinoma of the intestinal neovagina or diversion colitis.

*Urinary Tract.* Jarolim [26] created a functional sigmoidal neovagina in five patients and stated that all patients could urinate while seated with no difficulty. After 36 rectosigmoid vaginoplasties (of which 28 in MtF patients), Kwun Kim et al. [37]

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**Table 5** Study characteristics and outcome of intestinal vaginoplasty

Study	Study design	Quality assessment	N (Total/MTF)	Surgical technique	Outcome complications	Outcome anatomy neovagina	Outcome sexual function	Outcome patient satisfaction	Outcome QoL	Follow-up
Bouman et al. [35]	Review	Moderate	Total 894 MTF 50 +	Sigmoid N686 Ileum N169 Laparotomy and laparoscopy	Sigmoid overall 6.4% Ileum overall 8.3% Introlitus stenosis S8.6% 11.2% Diffuse stenosis S3.5% 13% Prolapse S7.7% 1 not reported Discharge S 0.7% Malodor S 9.5% Diversion colitis 0% Cancer 0% Introlitus stenosis 9/12 (75%) Painful suture line mucosa-perineal skin 6/12 (50%) Discharge/bleeding/inflammation 4/12 (33%) Painful contractions neovagina 3/12 (25%) Rectovaginal fistula 1/12 (8%) Voiding without difficulties 100%	Sigmoid Depth 11.5–13.0 cm Diam 3.7–4.0 cm Ileum Depth 10.5–18.0 cm Diam 2.5–4.5 cm	Sexual activity 74.2% Satisfactory 85.7% Mean FSFI 24.8–28.9 (range 11.5–35.7) Dyspareunia 24.7% Vaginal bleeding 8.8%	—	—	Sigmoid mean 19.7 months (18 months–12 years). Ileum mean 49.9 months (14–34.6 months)
Hage et al. [36]	Retrospective	Weak	MTF 12	Rectosigmoid	Stenosis 2/7 (29%) Peritonitis 1/7 (14%) Painful scarring 0 (0%) Neuroma 0 (0%) Rectovaginal fistula 0 (0%) Painful contractions 0 (0%) Ulcerative colitis 0 (0%) Adenocarcinoma 0 (0%) Abdominal mucocele 0 (0%) Stenosis N2 (6%) Voiding disorder N2 (6%) Rectovaginal fistula N1 (3%) Rectovaginal protrusion N3 (8%)	—	—	—	—	Mean 12 months (2 months–7 years)
Jarolim [26]	Retrospective	Weak	MTF 5	Sigmoid		—	—	—	—	—
Karim et al. [14]	Retrospective	Weak	MTF 7	Sigmoid		—	—	—	—	Mean 6.4 years (1–13 years)
Kwon Kim et al. [37]	Retrospective	Weak	Total 36 MTF 28	Rectosigmoid		Depth mean 12 cm Diam mean 3.9 cm (MTF)	Sexual activity 22/28 (79%) Vaginal bleeding 2 (6%) Excessive discharge 3 (8%) Dyspareunia 1 (3%) Orgasm 89% male type 42%	"Cosmetic configuration" Good 24/28 (86%) Fair 4/28 (14%)	—	Mean 5 years (1–10 years)
Djordjevic et al. [38]	Retrospective	Moderate	Total 86 MTF 27	Rectosigmoid Laparotomy	Mucosal prolapse 7/86 (8%) Wound infection/dehiscence 0 (0%) Urethral/rectal injuries 0 (0%)	Depth mean 12 cm Diam mean 3.4 cm (MTF)	FSFI (all patients) mean 28.9 (11.5–35.7) Satisfactory sexual function 69/86 (80.23%) MTF 21/27 (77.8%)	"Good esthetic appearance" 77/86 (89.5%) Beck Depression Index (BDI) mean 7.55 (0–42) MTF: mild 15% moderate 4% severe 4%	—	Mean 47 months (8–114 months)
Wedler et al. [39]	Retrospective	Weak	MTF 11	Sigmoid Laparotomy 2 Laparoscopy 9	Abdominal wall infection 1/11 (9%) Intestinal complications 0/11 (0%) Stenosis 2/11 (18%) Prolapse, neuroma, fistulas, bleeding 0/11 (0%) Intraoperative complications 0/86 (0%) Postoperative complications: Intra-abdominal hemorrhage 1/86 (1%) Urethral meatal stenosis 1/86 (1%) Intestinal obstruction 1/86 (1%) Vaginal stenosis 5/86 (6%) Tumor 0/86 (0%) Prolapse 0/86 (0%) As described above	—	Sexual intercourse 7/11 (63%)	—	—	—
Wu et al. [33]	Retrospective	Moderate	Total 86 MTF 12	Ileum laparoscopic		Depth 15–18 cm Width 2.5–4.0 cm	Frequent orgasms >50% Adequate lubrication 90% Dyspareunia 0/86 (0%) Vaginal bleeding 0/86 (0%)	—	—	Mean 14 months (12–18 months)
Wu et al. [40]	Retrospective	Moderate	Total 80 MTF 11	Ileum laparoscopic		As described above	As described above	—	—	Mean 18 months (16–22 months)

Diam. = diameter; FSFI = Female Sexual Function Index; MTF = male-to-female

noted two patients with voiding disorders due to partial obstruction of the urethral meatus. The obstructive tissue could be excised successfully.

*Gastrointestinal.* In a transgender group of 30 patients, there was one case of abdominal wall infection and one case of peritonitis [36,39,41]. The first patient was successfully treated with antibiotics; the second patient required a re-laparotomy and a necrosed neovagina was resected. Wu et al. [33] observed one patient with an intestinal obstruction after 86 laparoscopic vaginoplasties with an ileal segment. No other gastrointestinal complications were reported in the included articles.

*Wound Healing Disorders.* Several authors mention that wound healing disorders, such as neuroma, painful scarring, and wound infection, did not occur in their patients [38,39,41]. In one study with 12 MtF patients, six patients complained about pain located on the suture line of the mucosa-perineal skin anastomosis [36].

*Unspecific Events.* No other serious adverse events were reported.

### Sexual Function

One year after bowel vaginoplasty, 63% [39] and 79% [37] of transgender patients were sexually active. Djordjevic et al. [38] report that 77.8% of transgenders have a satisfactory sexual function, based on FSFI scores. According to the FSFI scores, there was no sexual dysfunction in 80.23% of cases in their combined (partially nontransgender) patient group. There was no significant difference between the vaginal agenesis and transgender groups.

### Patient Satisfaction and QoL

Cosmetic configuration of the rectosigmoid neovagina was assessed in 28 MtF patients and was “good” in 88.9% and fair in 11.1% [37]. Djordjevic et al. [38] found a “good aesthetic appearance” in 89.5% of treated MtF patients. It is unclear if the assessment was made by the physician or patient and which criteria were used. In addition to this, the surgical technique for labioplasty in these patients was not reported.

Psychological outcome after surgery was evaluated in 86 patients (including 27 transgenders), using the Beck Depression Inventory (BDI), a multiple choice self-report questionnaire for measuring the severity of depression [38]. Of the 27

transgender patients, scores of eight patients (30%) were consistent with depression according to the BDI. These results were not compared with BDI scores prior to surgery.

### Experimental

One clinical pilot study met the inclusion criteria. Dessy et al. [42] operated on six MtF patients and covered the neovaginal walls with cultured autologous oral epithelium in a three-step procedure (oral biopsy, neovaginal cavity formation and insertion of gauze with oral epithelial cells, and clitorolabiaplasty). Complications were rectovaginal fistula (n = 1), clitoris necrosis (n = 1), surgical revision of the labia (n = 1), and short vagina, which could be deepened in a redo operation (n = 1). Neovaginal depth was 12–14 cm with a width of 3–4 cm. Biopsies of the neovagina showed a normal oral mucosal epithelium. According to the authors, all patients were sexually active after the operation and were happy with their sexual function.

### Discussion

By reviewing literature since 1995, a trend was visible in the surgeon’s preference for neovaginoplasty technique. Before 2000, the use of nongenital skin grafts and flaps was a common treatment option, but although results were poorly reported and obtained from small patient groups, complications seemed to be present in a great proportion of patients. Especially split thickness skin grafts were significantly associated with neovaginal stricture. These findings, possibly in combination with clinically observed poor results, may justify the fact that this technique alone has been abandoned as a first-line therapy.

Since 2000, research groups have been reporting on the outcome of the penile skin inversion technique, and it became the most investigated and therefore most “evidence-based” technique for vaginoplasty in MtF transgenders. However, almost all evidence that has been presented so far is of low to intermediate quality. No standardized surgical technique is available, and each research group uses different outcome measures. In addition to this, methods are poorly described in most articles. This hampers the interpretation of results, and it is debatable if these results are even comparable. There is also a possibility that the patient groups of the included studies overlap, as some articles were published by the same author or institute.

When penoscrotal or urethral flaps are used in addition to the inverted penile skin flap, major complications such as necrosis and vaginal wall rupture were reported more frequently, but this was only investigated in a small number of patients.

Bowel vaginoplasty for transgenders was already a research topic in the late 1990s, but its efficacy was only based on small patient numbers and unclear outcome measures. In the past 5 years, investigators have been trying to obtain more evidence for this surgical technique, but because of heterogeneous patient groups (in which gynecological and gender patients are both included) and for which outcomes are only reported for a total of 109 MtF patients in literature, the applicability in transgender women is still uncertain.

Although the data of the included articles were not pooled, our results indicate that there were less neovaginal, wound healing, and even gastrointestinal complications in the bowel vaginoplasty group, compared with the penile skin inversion technique. Aesthetical outcome was comparable. Sexual function was reasonably good in both techniques, but these results could not be compared due to different outcome measures. Although neovaginal carcinoma and diversion colitis have been reported in literature [43–45] and have been feared ever since, they were not observed in the included studies. However, in most studies, follow-up was not longer than 3 years, and a longer follow-up would be necessary to assess the true prevalence of these long-term complications.

These results suggest that intestinal vaginoplasty is not inferior to the penile skin inversion technique, but there may be an over- or underestimation of efficacy and complications due to insufficient sample sizes. Superiority of one technique can only be evaluated in a large-scale prospective comparative trial.

Also in biological women with vaginal aplasia, the ideal modality for the construction of a neovagina remains unclear [12]. One of the common surgical techniques for the creation of a neovagina in these patients is the use of the peritoneum (Davydov procedure) [12,46].

An interesting finding is that the only available randomized controlled trial regarding vaginoplasty for vaginal aplasia compared the use of bowel with a laparoscopic peritoneal approach (Davydov procedure). The results were in favor of the laparoscopic peritoneal approach, with significant smaller intraoperative blood loss, operative

time, and decreased duration of inpatient stay. The mean neovaginal length did not significantly differ between the two groups; however, abdominal discomfort and foul vaginal secretions during intercourse were increased in the bowel vaginoplasty group [12,47]. In addition to this, neovaginal prolapse has never been reported after the Davydov procedure. Peritoneum has never been used for the lining of the neovagina in MtF transgenders. It could potentially also benefit this patient group, but to date no clinical evidence is available to support this hypothesis.

The use of cultured autologous epithelial cells for neovaginal construction [42] is still controversial as it has only been performed in a small patient group. The same applies to other experimental techniques such as complete tissue engineering of the vagina, using scaffolds seeded with vaginal epithelial cells. This method has already been investigated in a preclinical [48] and clinical setting with vaginal aplasia patients [49] with promising results. However, this method cannot easily be used in transgender women, as no autologous vaginal epithelial cells can be harvested in MtF transgenders. Nevertheless, with regard to the growing knowledge in the field of bio regenerative medicine, we believe that tissue engineering may offer attractive new options for (transgender) neovaginoplasty in the future.

### Conclusion and Recommendation

It is impossible to identify the “best available” technique for vaginoplasty in MtF patients due to a lack of high-quality evidence and the heterogeneity of surgical techniques, patient groups, and outcome measures. For now, the penile skin inversion technique is the most researched method, and surgical outcome and sexual function are generally acceptable to good. The outcome of vaginoplasty with pedicled bowel segments is less frequently reported in MtF patients but does not seem to be inferior to the penile skin inversion technique. Ideally, a randomized controlled trial would differentiate between these techniques, but this study design is hard to realize in surgical fields. In addition, it is a logical first step to use the easily accessible penile skin before considering abdominal surgery. The benefit of additional urethral and penoscrotal flaps cannot be confirmed in current literature, and there is a limited role for nongenital skin flaps and grafts as a primary surgical option. The role of tissue engineering and cultured autologous cells for



vaginoplasty has to be further clarified in future research.

There is a need for prospective studies with standardized surgical procedures, larger patient groups, and a longer follow-up period. Uniformity in outcome measurement tools such as validated questionnaires and scores for sexual function and QoL is mandatory for comparability between studies and correct interpretation of obtained data. The use of these patient-reported outcome measures will enable researchers and physicians to better evaluate the outcome of gender reassignment surgery from the patient's perspective.

Unless these improvements are made in future scientific research, the ideal method for the creation of a neovagina in MtF transgender patients cannot be identified, and the choice for a certain technique will stay an expertise-based decision rather than evidence-based medicine.

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